



Billing Code 4410-09-M

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
Importer of Controlled Substances
Notice of Application
Almac Clinical Services, Inc., (ACSI)

Pursuant to Title 21 Code of Federal Regulations
1301.34 (a), this is notice that on March 5, 2013, Almac
Clinical Services, Inc., (ACSI), 25 Fretz Road, Souderton,
Pennsylvania 18964, made application by renewal to the Drug
Enforcement Administration (DEA) to be registered as an
importer of the following basic classes of controlled
substances:

Drug	Schedule
Oxycodone (9143)	II
Hydromorphone (9150)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to import small quantities of the
listed controlled substances in dosage form to conduct
clinical trials.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage forms for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 USC § 952(a)(2)(B)) may, in the circumstances set forth in 21 USC § 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR § 1301.43 and in such form as prescribed by 21 CFR § 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION].

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR §

1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic classes of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 USC § 958(a); 21 USC § 823(a); and 21 CFR § 1301.34(b), (c), (d), (e), and (f) are satisfied.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

DATED: April 10, 2013

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